

SECTION 2.**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

K111031

JUL - 8 2011

2.510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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TRADE NAME	PAINfusor Catheter
COMMON NAME	Anesthesia Conduction Catheter
CLASSIFICATION NAME	Catheter, conduction, anesthetic
DEVICE CLASSIFICATION	21 CFR §868.5120
PRODUCT CODES	73 BSO
PREDICATE DEVICE	I-Flow Corporation's On-Q SliverSoaker Catheter, (K051401), and Pajunk's Wound Infiltration Catheter Kit (K080675).

SUBSTANTIALLY EQUIVALENT TO:

The PAINfusor Catheter is substantially equivalent to the I-Flow Corporation's On-Q SliverSoaker Catheter, (K051401), and Pajunk's Wound Infiltration Catheter Kit (K080675). Both predicate devices are Class II devices, and are substantially equivalent to the PAINfusor Catheter in intended use and technological features.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The PAINfusor Catheter is a closed tip multi-holed catheter with a fenestrated length that incorporates micro-holes in a helical pattern that allow for homogenous flow of analgesia into a surgical wound. The PAINfusor Catheter is radiopaque and has graduated markings along the length of the catheter for positional reference.

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It is supplied and packaged as a kit with a peel-away introducer needle, occlusive wound dressing and catheter securement adhesive.

INDICATIONS FOR USE:

The PAINfusor Catheter, along with related accessory devices, is intended for use to provide continuous or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites for preoperative, perioperative and postoperative pain management. Routes of administration may be intraoperative or percutaneous.

TECHNICAL CHARACTERISTICS:

The PAINfusor Catheter delivers local anesthetics or narcotics through a fenestrated section at the distal end of a closed catheter. The materials incorporated in the PAINfusor Catheter are substantially equivalent to those contained in the predicate devices.

PERFORMANCE DATA:

Safety and performance of the PAINfusor Catheter have been validated through bench, biocompatibility, sterilization, packaging, and shelf-life testing. Bench testing confirms that the PAINfusor Catheter can be used according to its intended use and in an equivalent manner to the predicate devices. Testing was conducted in accordance with ISO 10555-1:1995 "Sterile, Single Use Intravascular Catheters- Part 1: General Requirements." Flow performance testing confirmed a low rate of flow reduction (<1%) when the PAINfusor catheter is used with different size elastomeric infusion pumps. Kink testing verified that the kinking diameter for the catheter is within the specified acceptable range for functional use of the catheter. A comparison between peel testing results for the occlusive wound dressing verified the sterilization process did not affect the adhesive strength. Sterilization and biocompatibility testing requirements listed in ISO 10555-1 were met.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The PAINFUSOR Catheter is an anesthesia conducting catheter substantially equivalent in intended use and mechanism of action to I-Flow Corporation's On-Q SliverSoaker Catheter, (K051401) and Pajunk's Wound Infiltration Catheter Kit (K080675). All three devices are intended to provide delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites for pain management. All three devices deliver medication through multiple holes in a fenestrated length of a closed tip catheter. The differences in fenestration pattern did not affect flow characteristics, as demonstrated by flow performance testing. Biocompatibility testing per ISO10993 ensures that, although the PAINfusor is constructed of different materials (Polyamide Pebax® vs. Polyamide (Nylon) for the On-Q SliverSoaker and Polyamide with an Internal stainless steel coil for the Pajunk's Wound Infiltration Catheter Kit), the PAINfusor Catheter is as safe as the predicate devices for its intended use. All tests indicate that the PAINfusor Catheter functions in an equivalent manner to the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Plan 1 Health, S.R.L.
C/O Ms. Sigi Caron
Regulatory and Clinical Consultant
Medtech Consultants, Incorporated
2400 Via Carillo
Palos Verdes Estates, California 90274

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Re: K111031
Trade/Device Name: PAINfusor Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: April 12, 2011
Received: April 14, 2011

Dear Ms. Caron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

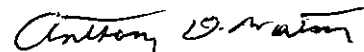
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

SECTION 1.

INDICATIONS FOR USE STATEMENT

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111031

Device Name: PAINfusor Catheter

Indications for Use:

The PAINfusor Catheter, along with related accessory devices, is intended for use to provide continuous or intermittent delivery of medication (such as local anesthetics or narcotics) to or around surgical wound sites for preoperative, perioperative and postoperative pain management. Routes of administration may be intraoperative or percutaneous.

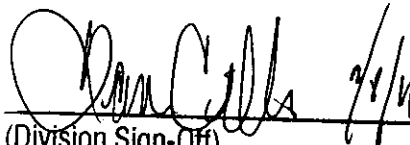
Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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